REMARKS

I. Status of the Claims

Claims 1-115 were originally filed. Claims 9, 10, 28-104, and 110 have been canceled. Claims 1-8, 11-27, 105-109, and 111-115 are currently under examination. Applicants note with appreciation that the Examiner has indicated the allowability of claims 1-4, 7, 8, 11-18, 20-27, 105-109, and 111-115.

II. Claim Rejections

A. Obviousness-Type of Double Patenting

The Examiner maintained the rejection of claims 5 and 19 under the judicially created doctrine of obviousness-type of double patenting, alleging that these two claims are unpatentable over claims 1-3 of U.S. Patent No. 6,592,877 ("the '877 patent"). Applicants respectfully traverse the rejection.

The subject matter of claims 1-3 of the '877 patent is an isolated fusion protein comprising four *M. tuberculosis* antigens: TbRa3 (SEQ ID NO:77), Tb38-1 (SEQ ID NO:88), TbH4 (SEQ ID NO:89), and 38kD (SEQ ID NO:155). In contrast, claim 5 of the present application is directed to a composition that contains a fusion protein comprising *M. tuberculosis* antigens MTb81 and Mo2, whereas claim 19 are directed to a composition that contains a fusion protein comprising at least two of *M. tuberculosis* antigens MTb81, Mo2, TbRa3, 38kD, Tb38-1 (MTb11), FL TbH4, HTCC#1 (Mtb40), TbH9, MTCC#2 (Mtb41), DPEP, DPPD, TbRa35, TbRa12, MTb59, MTb82, Erd14 (Mtb16), FL TbRa35 (Mtb32A), DPV (Mtb8.4), MSL (Mtb9.8), MTI (Mtb9.9A, also known as MTI-A), ESAT-6, α-crystalline, and 85 complex.

Because claim 5 relates to a fusion protein that comprises two *M. tuberculosis* antigens different from the four antigens named in claims 1-3 of the '877 patent, Applicants do not believe claim 5 is obvious in view of claims 1-3 of the '877 patent. Although at first glance claim 19 appears to refer to all four *M. tuberculosis* antigens named in claims 1-3 of the '877 patent, claim 19 in fact names an antigen ***FL TbH4*** instead of TbH4 (SEQ ID NO:89) in the

claims of the '877 patent. A close inspection of the actual amino acid sequences of FL TbH4 of the present application (which is SEQ ID NO:12, according to description on page 6 line 3 of the specification) and TbH4 of the '877 patent (which is SEQ ID NO:89) reveals that the two sequences are significantly different: SEQ ID NO:12 of the present application is a peptide of 286 amino acids and SEQ ID NO:89 of the '877 patent is a peptide of 166 amino acids (see Exhibit I). It is therefore clear that the fusion protein relevant to claim 19 is defined by a combination of *M. tuberculosis* antigens, not all of which are named in claims 1-3 of the '877 patent. Further, claim 19 does not explicitly name all four antigens recited in claims 1-3 of the '877 patent. Applicants therefore contend that the fusion protein of claim 19 is not obvious over claims 1-3 of the '877 patent.

As such, the withdrawal of the obviousness-type double patenting rejection is respectfully requested.

B. 35 U.S.C. §112, Second Paragraph

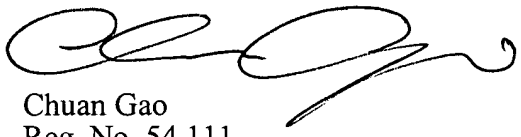
The Examiner rejected claim 6 under 35 U.S.C. §112, second paragraph, for its dependency from a rejected base claim. As discussed above, the only other outstanding rejection, the obviousness-type double patenting rejection, has been properly addressed. The rejection of claim 6 is therefore obviated.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance and an action to that end is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,



Chuan Gao
Reg. No. 54,111

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 4115-576-0200
Fax: 415-576-0300

Attachments (Exhibit I: SEQ ID NO:89 of U.S. Patent No. 6,592,877 and SEQ ID NO:12 of the present application)
CG:cg
60489108 v1

-continued

```
1               5                   10                  15

Ser Gly Asp Leu Lys Thr Gln Ile Asp Gln Val Glu Ser Thr Ala Gly
            20                  25                  30

Ser Leu Gln Gly Gln Trp Arg Gly Ala Ala Gly Thr Ala Ala Gln Ala
        35                  40                  45

Ala Val Val Arg Phe Gln Glu Ala Ala Asn Lys Gln Lys Gln Glu Leu
    50                  55                  60

Asp Glu Ile Ser Thr Asn Ile Arg Gln Ala Gly Val Gln Tyr Ser Arg
65                  70                  75                  80

Ala Asp Glu Glu Gln Gln Gln Ala Leu Ser Ser Gln Met Gly Phe
                85                  90                  95
```

(2) INFORMATION FOR SEQ ID NO:89:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 166 amino acids
(B) TYPE: amino acid
(C) STRANDEDNESS: single
(D) TOPOLOGY: linear

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:89:

```
Met Thr Gln Ser Gln Thr Val Thr Val Asp Gln Gln Glu Ile Leu Asn
1               5                   10                  15

Arg Ala Asn Glu Val Glu Ala Pro Met Ala Asp Pro Pro Thr Asp Val
            20                  25                  30

Pro Ile Thr Pro Cys Glu Leu Thr Xaa Xaa Lys Asn Ala Ala Gln Gln
        35                  40                  45

Xaa Val Leu Ser Ala Asp Asn Met Arg Glu Tyr Leu Ala Ala Gly Ala
    50                  55                  60

Lys Glu Arg Gln Arg Leu Ala Thr Ser Leu Arg Asn Ala Ala Lys Xaa
65                  70                  75                  80

Tyr Gly Glu Val Asp Glu Glu Ala Ala Thr Ala Leu Asp Asn Asp Gly
                85                  90                  95

Glu Gly Thr Val Gln Ala Glu Ser Ala Gly Ala Val Gly Gly Asp Ser
            100                 105                 110

Ser Ala Glu Leu Thr Asp Thr Pro Arg Val Ala Thr Ala Gly Glu Pro
        115                 120                 125

Asn Phe Met Asp Leu Lys Glu Ala Ala Arg Lys Leu Glu Thr Gly Asp
    130                 135                 140

Gln Gly Ala Ser Leu Ala His Xaa Gly Asp Gly Trp Asn Thr Xaa Thr
145                 150                 155                 160

Leu Thr Leu Gln Gly Asp
                165
```

(2) INFORMATION FOR SEQ ID NO:90:

(i) SEQUENCE CHARACTERISTICS:
(A) LENGTH: 5 amino acids
(B) TYPE: amino acid
(C) STRANDEDNESS: single
(D) TOPOLOGY: linear

(xi) SEQUENCE DESCRIPTION: SEQ ID NO:90:

```
Arg Ala Glu Arg Met
1               5
```

(2) INFORMATION FOR SEQ ID NO:91:

(i) SEQUENCE CHARACTERISTICS:

<400> 10
Thr Asp Ala Ala Thr Leu Ala Gln Glu Ala Gly Asn Phe Glu Arg Ile
1 5 10 15

Ser Gly Asp Leu Lys Thr Gln Ile Asp Gln Val Glu Ser Thr Ala Gly
20 25 30

Ser Leu Gln Gly Gln Trp Arg Gly Ala Ala Gly Thr Ala Ala Gln Ala
35 40 45

Ala Val Val Arg Phe Gln Glu Ala Ala Asn Lys Gln Lys Gln Glu Leu
50 55 60

Asp Glu Ile Ser Thr Asn Ile Arg Gln Ala Gly Val Gln Tyr Ser Arg
65 70 75 80

Ala Asp Glu Glu Gln Gln Gln Ala Leu Ser Ser Gln Met Gly Phe
85 90 95

<210> 11
<211> 702
<212> DNA
<213> Mycobacterium tuberculosis

<220>
<223> TbH4

<220>
<221> modified_base
<222> (1)..(702)
<223> n = g, a, c or t

<400> 11
cggcacgagg atcggtaccc cgcggcatcg gcagctgccg attcgccggg tttccccacc 60
cgaggaaagc cgctaccaga tggcgctgcc gaagtagggc gatccgttcg cgatgccggc 120
atgaacgggc ggcatcaaat tagtgcagga acctttcagt ttagcgacga taatggctat 180
agcactaagg aggatgatcc gatatgacgc agtcgcagac cgtgacggtg gatcagcaag 240
agattttgaa cagggccaac gaggtggagg ccccgatggc ggacccaccg actgatgtcc 300
ccatcacacc gtgcgaactc acggnggnta aaaacgccgc ccaacagntg gtnttgtccg 360
ccgacaacat gcgggaatac ctggcggccg gtgccaaaga gcggcagcgt ctggcgacct 420
cgctgcgcaa cgcggccaag gngtatggcg aggttgatga ggaggctgcg accgcgctgg 480
acaacgacgg cgaaggaact gtgcaggcag aatcggccgg ggccgtcgga ggggacagtt 540
cggccgaact aaccgatacg ccgagggtgg ccacggccgg tgaacccaac ttcatggatc 600
tcaaagaagc ggcaaggaag ctcgaaacgg gcgaccaagg cgcatcgctc gcgcactgng 660
gggatgggtg gaacacttnc accctgacgc tgcaaggcga cg 702

<210> 12
<211> 286
<212> PRT
<213> Mycobacterium tuberculosis

<220>
<223> TbH4

<220>
<221> MOD_RES
<222> (1)..(286)
<223> Xaa = any amino acid

<400> 12

```
Gly Asp Ser Phe Trp Ala Ala Ala Asp Gln Met Ala Arg Gly Phe Val
 1               5                  10                  15

Leu Gly Ala Thr Ala Gly Arg Thr Thr Leu Thr Gly Glu Gly Leu Gln
            20                  25                  30

His Ala Asp Gly His Ser Leu Leu Leu Asp Ala Thr Asn Pro Ala Val
        35                  40                  45

Val Ala Tyr Asp Pro Ala Phe Ala Tyr Glu Ile Gly Tyr Ile Xaa Glu
    50                  55                  60

Ser Gly Leu Ala Arg Met Cys Gly Glu Asn Pro Glu Asn Ile Phe Phe
65                  70                  75                  80

Tyr Ile Thr Val Tyr Asn Glu Pro Tyr Val Gln Pro Pro Glu Pro Glu
                85                  90                  95

Asn Phe Asp Pro Glu Gly Val Leu Gly Gly Ile Tyr Arg Tyr His Ala
            100                 105                 110

Ala Thr Glu Gln Arg Thr Asn Lys Xaa Gln Ile Leu Ala Ser Gly Val
        115                 120                 125

Ala Met Pro Ala Ala Leu Arg Ala Ala Gln Met Leu Ala Ala Glu Trp
    130                 135                 140

Asp Val Ala Ala Asp Val Trp Ser Val Thr Ser Trp Gly Glu Leu Asn
145                 150                 155                 160

Arg Asp Gly Val Val Ile Glu Thr Glu Lys Leu Arg His Pro Asp Arg
                165                 170                 175

Pro Ala Gly Val Pro Tyr Val Thr Arg Ala Leu Glu Asn Ala Arg Gly
            180                 185                 190

Pro Val Ile Ala Val Ser Asp Trp Met Arg Ala Val Pro Glu Gln Ile
        195                 200                 205

Arg Pro Trp Val Pro Gly Thr Tyr Leu Thr Leu Gly Thr Asp Gly Phe
    210                 215                 220

Gly Phe Ser Asp Thr Arg Pro Ala Gly Arg Arg Tyr Phe Asn Thr Asp
225                 230                 235                 240

Ala Glu Ser Gln Val Gly Arg Gly Phe Gly Arg Gly Trp Pro Gly Arg
                245                 250                 255

Arg Val Asn Ile Asp Pro Phe Gly Ala Gly Arg Gly Pro Pro Ala Gln
            260                 265                 270

Leu Pro Gly Phe Asp Glu Gly Gly Gly Leu Arg Pro Xaa Lys
        275                 280                 285
```

<210> 13
<211> 1200
<212> DNA
<213> Mycobacterium tuberculosis